



PATENT  
Docket No. GZ 2104.20  
GZ Ref. 5040 US2

**CERTIFICATE OF MAILING**

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Dated:

August 21, 2002

Mary R. Zimmerman

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application for:

Charles A. NICOLETTE

Serial No.: 10/079,699

Filing Date: February 19, 2002

For: PAR-3 COMPOUNDS FOR THERAPY  
AND DIAGNOSIS AND METHODS  
FOR USING SAME

Examiner: Not Yet Assigned

Group Art Unit: 1614

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Commissioner for Patents  
Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached forms PTO-1449a and PTO-1449b are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. The Examiner is requested to make these documents of record.

**I. Timing of the Information Disclosure Statement:**

This Information Disclosure Statement is filed:

- ☐ With the new patent application submitted herewith (37 C.F.R. § 1.97(a)).
- ☐ Within three months after the filing date of the application or within three months after the date of entry of the national stage of a PCT application as set forth in 37 C.F.R. § 1.491.

- ☒ Before the mailing date of a first Office action on the merits. In the event, however, that an Office Action has crossed in the mail with this Information Disclosure Statement, the Commissioner is hereby authorized to charge Deposit Account No. 50-1189 for any fees required pursuant to 37 C.F.R. §§ 1.17(p) or 1.17(i)(1).

This Information Disclosure Statement is filed:

- ☐ After the first Office Action and more than three months after the application's filing date; or PCT national stage date of entry filing but, as far as is known to the undersigned, prior to the mailing date of either a final rejection or a notice of allowance, whichever occurs first, and the Commissioner is hereby authorized to charge Deposit Account No. [ ] for the fee (\$180) set forth in 37 C.F.R. § 1.17(p) and any additional required fees.

This Information Disclosure Statement is filed:

- ☐ After the mailing date of either a final rejection or a notice of allowance, whichever occurred first, and is accompanied by the fee (\$180.00) set forth in 37 C.F.R. § 1.17(i)(1) and a certification as specified in 37 C.F.R. § 1.97(e), as checked below. This document is to be considered as a petition requesting consideration of the Information Disclosure Statement.

The undersigned certifies that:

- ☐ Each item of information contained in the Information Disclosure Statement was first cited in any communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

## II. Copies of the Cited Items:

- ☐ Copies of all of the items listed on the attached Form PTO-1449 are enclosed.
- ☐ Copies of only the following items listed on the attached Form PTO-1449 are enclosed: \_\_\_\_\_.
- ☒ Copies of the items listed in the attached Form PTO-1449a and b are not supplied because they were previously cited by or submitted to the Patent Office in a prior Application No. 09/931,969 filed August 17, 2001 and relied

upon in this application for an earlier filing date under 35 U.S.C § 120.  
See 37 C.F.R. § 1.98(d).

- ☐ Copies of those items which are marked with an asterisk (\*\*) in the attached Form PTO-1499 were cited in a foreign examination report in a related case. A copy of the search report and the cited references not already of record in this application are attached hereto.

### III. Concise Explanation of Relevance:

- ☒ A concise explanation of relevance of the items listed on Form PTO-1449 is not given.
- ☐ A concise explanation of relevance of [some of] the items listed on Form PTO-1449 is in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references (copy attached).

### IV. Related Applications:

- ☒ Applicants bring to the Office's attention the following related, co-pending application(s): U.S. Serial No.: 09/931,969, filed August 17, 2001 and PCT Application Nos. PCT/US01/25708 and PCT/US02/05322, filed August 17, 2001 and February 19, 2002, respectively.

### V. Conclusion:

Citation of the above documents shall not be construed as:

1. an admission that the documents are necessarily prior art with respect to the instant invention;
2. a representation that a search has been made, other than as described above; or
3. an admission that the information cited herein is, or is considered to be, material to patentability as defined in § 1.56(b).

It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached form PTO 1449 with initials or other appropriate marks. The Commissioner is hereby authorized to charge Deposit Account No. 50-1189, billing reference number: 19442-7254 for any additional fees required in connection with the filing of this Information Disclosure Statement.

Respectfully submitted,

Dated: Aug. 21, 2002

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

Application Number 10/079,699  
 Filing Date February 19, 2002  
 First Named Inventor Charles A NICOLETTE  
 Art Unit 1614  
 Examiner Name Not Yet Assigned  
 Attorney Docket Number GZ 2104.20

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	1	US-4,683,195	07/28/87	Mullis et al.	
	2	US-4,683,202	07/28/87	Mullis	
	3	US-4,754,065	06/28/88	Levenson et al.	
	4	US-4,800,159	01/24/89	Mullis et al.	
	5	US-5,440,013	08/08/95	Kahn	
	6	US-5,837,249	11/17/98	Heber-Katz et al.	

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## FOREIGN PATENT DOCUMENTS

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		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	7	WO 96/23060	08/01/96	The Government of the United States of America		
	8	EP 0 702 082 A1	03/20/96	Hagiware et al.		

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 4

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Application Number	10/079,699
Filing Date	February 19, 2002
First Named Inventor	Charles A. NICOLETTE
Art Unit	1614
Examiner Name	Not Yet Assigned
Attorney Docket Number	GZ 2104.20

**OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published	T <sup>2</sup>
	1	ALTMAN, J.D. et al. "Phenotypic analysis of antigen-specific T lymphocytes" <i>Science</i> (1996) <b>274(5284)</b> :94-96	
	2	BERTONI, R. et al. "Human class I supertypes and CTL repertoires extend to chimpanzees" <i>J. Immunol.</i> (1998) <b>161</b> :4447-4455	
	3	BOCZKOWSKI, D. et al. "Dendritic cells pulsed with RNA are potent antigen-presenting cells in vitro and in vivo" <i>J. Exp. Med.</i> (1996) <b>184</b> :465-472	
	4	BORDIGNON, C. et al. "Retroviral vector-mediated high-efficiency expression of adenosine deaminase (ADA) in hematopoietic long-term cultures of ADA-deficient marrow cells" <i>PNAS USA</i> (1989) <b>86</b> :6748-6752	
	5	CARTER, B.J. "Adeno-associated virus vectors" <i>Curr. Op. Biotechnol.</i> (1992) <b>3</b> :533-539	
	6	CARUSO, A. et al. "Flow cytometric analysis of activation markers on stimulated T cells and their correlation with cell proliferation" <i>Cytometry</i> (1997) <b>27</b> :71-76	
	7	COCKLE, S.M. et al. "Thyrotrophin-releasing hormone-related polypeptides in rabbit prostate and semen are different from those in rabbit hypothalamus" <i>J. Endocrinology</i> (1989) <b>120</b> : 31-36	
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	9	CORRELL, P.H. et al. "Production of human glucocerebrosidase in mice after retroviral gene transfer into multipotential hematopoietic progenitor cells" <i>PNAS USA</i> (1989) <b>86</b> :8912-8916	
	10	COULIE, P.G. "Human tumour antigens recognized by T cells: new perspectives for anti-cancer vaccines?" <i>Molec. Med. Today</i> (1997) <b>3</b> :261-268	
	11	CULVER, K. et al. "Lymphocytes as cellular vehicles for gene therapy in mouse and man" <i>PNAS USA</i> (1991) <b>88</b> :3155-3159	
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	14	DiMAIO, J. and B. BELLEAU "Synthesis of chiral piperazin-2-ones as model peptidomimetics" <i>J. Chem. Soc. Perkin Trans.</i> (1989) <b>1(9)</b> :1687-1689	
	15	FELTKAMP, M.C.W. et al. "Competition inhibition of cytotoxic T-lymphocyte (CTL) lysis, a more sensitive method to identify candidate CTL epitopes than induction of antibody-detected MHC class I stabilization" <i>Immunol. Lett.</i> (1995) <b>47</b> :1-8	
	16	FERGUSON, M.A.J. and A.F. WILLIAMS "Cell-surface anchoring of proteins via glycosyl-phosphatidylinositol structures" <i>Ann. Rev. Biochem.</i> (1988) <b>57</b> :285-320	
	17	FISCHER, E. et al. "Tissue factor-initiated thrombin generation activates the signaling thrombin receptor on malignant melanoma cells" <i>Cancer Research</i> (1995) <b>55</b> :1629-1632	
	18	FUJIIHASHI, K. et al. "Cytokine-specific ELISPOT assay single cell analysis of IL-2, IL-4 and IL-6 producing cells" <i>J. Immunol. Meth.</i> (1993) <b>160</b> :181-189	
	19	GARVEY, D.S. et al. "3,4-disubstituted $\gamma$ -lactam rings as conformationally constrained mimics of peptide derivatives containing aspartic acid or norleucine" <i>J. Org. Chem.</i> (1990) <b>55(3)</b> :936-940	
	20	GORELIK, E. "Augmentation of the antimetastatic effect of anticoagulant drugs by immunostimulation in mice" <i>Cancer Research</i> (1987) <b>47</b> :809-815	

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## OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

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	21	HENRIKSON, K.P. et al. "Role of thrombin receptor in breast cancer invasiveness" <i>British J Cancer</i> (1999) <b>79</b> (3/4):401-406	
	22	HRUBY, V.J. "Conformational restrictions of biologically active peptides via amino acid side chain groups" <i>Life Sciences</i> (1982) <b>31</b> :189-199	
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	25	ISHIHARA, H. et al. "Protease-activated receptor 3 is a second thrombin receptor in humans" <i>Nature</i> (1997) <b>386</b> :502-506	
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	28	KAHN, M. and S. BERTENSHAW "The incorporation of $\beta$ -turn prosthetic units into Merrifield solid phase peptide synthesis" <i>Tetrahedron Lett.</i> (1989) <b>30</b> (18):2317-2320	
	29	KARLSSON, S. et al. "Stable gene transfer and tissue-specific expression of a human globin gene using adenoviral vectors" <i>The EMBO J.</i> (1986) <b>5</b> (9):2377-2385	
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	32	KAZMIERSKI, W. M. and V.J. HRUBY "Asymmetric synthesis of topographically constrained amino acids: synthesis of the optically pure isomers of $\alpha$ , $\beta$ -dimethyl-phenylalanine and $\alpha$ , $\beta$ -dimethyl-1,2,3,4-tetrahydroisoquinoline-3-carboxylic acid" <i>Tetrahedron Lett.</i> (1991) <b>32</b> (41):5769-5772	
	33	KAZMIERSKI, W.M. et al. "Topographic design of peptide neurotransmitters and hormones on stable backbone templates: relation of conformation and dynamics to bioactivity" <i>J. Am. Chem. Soc.</i> (1991) <b>113</b> :2275-2283	
	34	KEMP, D.S. and P.E. McNAMARA "Conformationally restricted cyclic nonapeptides derived from L-cysteine and LL-3-amino-2-piperidone-6-carboxylic acid (LL-Acp), a potent $\beta$ -turn-inducing dipeptide analogue" <i>J. Org. Chem.</i> (1985) <b>50</b> :5834-5838	
	35	KEMP, D.S. and B.R. BOWEN "Conformational analysis of peptide-functionalized diacylaminoepindolidiones 'H NMR evidence for $\beta$ -sheet formation" <i>Tetrahedron Lett.</i> (1988) <b>29</b> (40):5081-5082	
	36	KEMP, D.S. and W.E. STITES "A convenient preparation of derivatives of 3(S)-amino-10(R)-carboxy-1,6-diaza-cyclodeca-2,7-dione The dilactam of L- $\alpha$ , $\gamma$ -diaminobutyric acid and D-glutamic acid: A $\beta$ -turn template" <i>Tetrahedron Lett.</i> (1988) <b>29</b> (40):5057-5060	
	37	KEMP, D.S. and T.P. CURRAN "(2, 5S, 8S, 11S)-1-acetyl-1, 4-diaza-3-keto-5-carboxy-10-thia-tricyclo-[2.8.0 <sup>4,8</sup> ]-nidecane, 1 the preferred conformation of 1 (1= $\alpha$ temp-OH) and its peptide conjugates $\alpha$ temp-L-(Ala) <sub>n</sub> -OR (n=1 to 4) and $\alpha$ -temp-L-Ala-L-Phe-Lys( $\epsilon$ Boc)-L-Lys( $\epsilon$ -Boc)-NHMe studies of templates for $\alpha$ -helix formation" <i>Tetrahedron Lett.</i> (1988) <b>29</b> (39):4935-4938	
	38	KEMP, D.S. and J.S. CARTER "Amino acid derivatives that stabilize secondary structures of polypeptides. 4. Practical synthesis of 4-(alkylamino)-3-cyano-6-azabicyclo[3.2.1]oct-3-enes (ben derivatives) as $\gamma$ -turn templates" <i>J. Org. Chem.</i> (1989) <b>54</b> :109-115	
	39	McGRORY, W.J. et al. "Short communications: A simple technique for the rescue of early region I mutation into infectious human adenovirus type 5" <i>Virology</i> (1988) <b>163</b> :614-617	
	40	MERRIFIELD, R.B. "New approaches to the chemical synthesis of peptides" <i>Recent Progress in Hormone Res.</i> (1967) <b>23</b> :451-482	
	41	MIYAKE, A. et al. "Synthesis and angiotensin converting enzyme inhibitory activity of 1,2,3,4-tetrahydroisoquinoline-3-carboxylic acid derivatives" <i>J. Takeda Res. Labs.</i> (1984) <b>43</b> (3/4):53-76	
	42	MOSIER, D.E. et al. "Resistance to human immunodeficiency virus 1 infection of SCID mice reconstituted with peripheral blood leukocytes from donors vaccinated with vaccinia gp160 and recombinant gp160" <i>PNAS. USA</i> (1993) <b>90</b> :2443-2447	

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	43	MUZCZYKA, N. "Use of adeno-associated virus as a general transduction vector for mammalian cells" <i>Curr. Top. Microbiol. Immunol.</i> (1992) <b>158</b> :97-129	
	44	NAGAI, U. and K. SATO "Synthesis of a bicyclic dipeptide with the shape of $\beta$ -turn central part" <i>Tetrahedron Lett.</i> (1985) <b>26</b> (5):647-650	
	45	NAIR, S. et al. "Soluble proteins delivered to dendritic cells via pH-sensitive liposomes induce primary cytotoxic T lymphocyte responses in vitro" <i>J. Exp. Med.</i> (1992) <b>175</b> :609-612	
	46	NEUBAUER, B.L. "Inhibitory effect of warfarin on the metastasis of the PAIII prostatic adenocarcinoma in the rat" <i>J. Urology</i> (1986) <b>135</b> :163-166	
	47	NIERODZIK, M.L. et al. "Protease-activated receptor 1 (PAR-1) required and rate-limiting for thrombin-enhanced experimental pulmonary metastasis" <i>Blood</i> (1998) <b>92</b> (10):3694-3700	
	48	OLSON, G.L. et al. "Design and synthesis of a protein $\beta$ -turn mimetic" <i>J. Am. Chem. Soc.</i> (1990) <b>112</b> :323-333	
	49	PAGLIA, P. et al. "Murine dendritic cells loaded in vitro with soluble protein prime cytotoxic T lymphocytes against tumor antigen in vivo" <i>J. Exp. Med.</i> (1996) <b>183</b> :317-322	
	50	PARDOLL, D.M. "Cancer vaccines" <i>Nature Med.</i> (1998) <b>4</b> (5 Suppl.):525-531	
	51	PARKER, K.C. et al. "Sequence motifs important for peptide binding to the human MHC class I molecule, HLA-A2" <i>J. Immunol.</i> (1992) <b>149</b> (11):3580-3587	
	52	PARKER, K.C. et al. "Peptide Binding to MHC Class I Molecules: Implications for Antigenic Peptide Prediction" <i>Immunol. Res.</i> (1995) <b>14</b> :34-57	
	53	PARKHURST, M.R. et al. "Improved induction of melanoma-reactive CTL with peptides from the melanoma antigen gp100 modified at HLA-A*0201-binding residues" <i>J. Immunol.</i> (1996) <b>157</b> :2539-2548	
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	55	RILL, D.R. et al. "An approach for the analysis of relapse and marrow reconstitution after autologous marrow transplantation using retrovirus-mediated gene transfer" <i>Blood</i> (1992) <b>79</b> (10):2694-2700	
	56	ROUSE, R.J.D. et al. "Induction in vitro of primary cytotoxic T-lymphocyte responses with DNA encoding herpes simplex virus proteins" <i>J. Virol.</i> (1994) <b>68</b> (9):5685-5689	
	57	SALAZAR, E. et al. "Agonist peptide from a cytotoxic T-lymphocyte epitope of human carcinoembryonic antigen stimulates production of TC1-type cytokines and increases tyrosine phosphorylation more efficiently than cognate peptide" <i>Int. J. Cancer</i> (2000) <b>85</b> :829-838	
	58	SAMANEN, J. et al. "5,5-dimethylthiazolidine-4-carboxylic acid (DTC) as a proline analog with restricted conformation" <i>Int. J. Peptide Protein Res.</i> (1990) <b>35</b> :501-509	
	59	SCHLESINGER, S. and T.W. DUBENSKY, Jr. "Alphavirus vectors for gene expression and vaccines" <i>Curr Opin Biotechnol.</i> (1999) <b>10</b> (5):434-439	
	60	SCHMIDT, V.A. et al. "The human proteinase-activated receptor-3 (PAR-3) gene" <i>J. Biol. Chem.</i> (12 June 1998) <b>273</b> (24):15061-15068	
	61	SCHULMAN, S.S. et al. "Incidence of cancer after prophylaxis with warfarin against recurrent venous thromboembolism" <i>The New Engl. J. Med.</i> (2000) <b>342</b> (26):1953-1958	
	62	SETTE, A. et al. "The relationship between class I binding affinity and immunogenicity of potential cytotoxic T cell epitopes" <i>J. Immunol.</i> (1994) <b>153</b> (12):5586-5592	
	63	SHIN, H. et al. "Thrombin receptor-mediated synovial proliferation in patients with rheumatoid arthritis" <i>Clinical Immunol. Immunopath.</i> (1995) <b>76</b> (3):225-233	
	64	SHIRAI, M. et al. "CTL responses of HLA-A2.1-transgenic mice specific for hepatitis C viral peptides predict epitopes for CTL of humans carrying HLA-A2.1" <i>J. Immunol.</i> (1995) <b>154</b> :2733-2742	
	65	STUBER, G. et al. "HLA-A0201 and HLA-B7 binding peptides in the EBV-encoded EBNA-1, EBNA-2 and BZLF-1 proteins detected in the MHC class I stabilization assay. Low proportion of binding motifs for several HLA class I alleles in EBNA-1" <i>Int. Immunol.</i> (1995) <b>7</b> (4):653-663	
	66	TAN, L. et al. "An improved assembly assay for peptide binding to HLA-B*2705 and H-2K*class I MHC molecules" <i>J. Immunol. Meth.</i> (1997) <b>209</b> (1):25-36	
	67	TANGUAY, S. and J.J. KILLION "Direct comparison of ELISPOT and ELISA-based assays for detection of individual cytokine-secreting cells" <i>Lymphokine Cytokine Res.</i> (1994) <b>13</b> (4):259-263	

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